Serial No.: 10/701,038   Atty.Dkt. No.: CLFR:235US

REMARKS

I.   Status of the Application

Claims 1-34 were pending. Claims 1-5, 7-14 and 16-26 are canceled. Claim 6, 30, 33 and 34 are amended to further clarify the claims and to address the new grounds of rejection presented in the final Office Action. Claims 6, 15, and 27-34 are currently pending. Support for the amendments can be found at least on page 13 and 14. The pending claims comply with the requirements of the final Office Action and are in condition for allowance, or alternatively are in better form for consideration on appeal.

II.   New Claim Objections

Claim 30 is objected to as being an improper dependent claim due to claim 30 failing to further limit claim 6. Claims 31-34 are objected to as being duplicates of claims 15, 27, 28, and 29, respectively. In light of the current amendments to claim 30 this objection is moot. Applicants respectfully request the withdrawal of the objection.

III. Rejection of Claims under 35 U.S.C. §112, first paragraph

Claims 6, 15, and 27-34 are rejected as failing to comply with written description requirement because the claims allegedly contain subject matter not described in the specification in such way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Action alleges that (A) no baseline sequence is provided for the *E. Canis* immunoreactive surface protein p153 gene and (B) none of the claimed proteins meet the written description requirement. The Action cites *Fiers v. Revel*, 984 F.2d 1164, 25 USPQ2d 1601, and *Amgen, Inc. v Chugai Pharmaceutical*, 927 F.2d 1200, 18 USPQ2d 1016, in support of the rejection. Applicants respectfully traverse.

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Applicants currently claim isolated and purified polypeptides of *Ehrlichia canis* immunoreactive surface protein p153 having an amino acid sequence shown in SEQ ID NO:2, having amino acids 361 to 663 of Genbank accession number AF252298 (GI:37528969), having amino acids 651 to 983 of Genbank accession number AF252298 (GI:37528969); and having amino acids 981 to 1406 of Genbank accession number AF252298 (GI:37528969). Genbank accession number AF252298 is disclosed on page 14 of the specification and a description of the peptide sequences are provided at least on page 13 of the specification. Based on Applicants disclosure of the full length nucleic acid sequence and polypeptide sequence of *E. canis* immunoreactive surface protein p153 as revised Genbank accession number AF252298 one of skill in the art would reasonably conclude that Applicants possessed the subject matter claimed. The full nucleic acid and polypeptide sequence are disclosed in the application.

Applicants clarify the claims by claiming the polypeptides directly as amino acid sequences instead of describing the polypeptides using the encoding DNA sequence. Applicants' specification provides written description for all amino acid sequences by reference to Genbank accession number AF252298 (*see* Genbank record, Exhibit A) as well as additional description of the use and relationship of the submission as it relates to the claimed invention. Page 14, line 9 to line 14 of the specification discloses the Genbank accession number (AF252298) and indicates the submission of the revised sequence as initially given Genbank accession number AY156950. However, the AF252298 record was updated to include the revised sequence instead of establishing the new accession number. The AF252298 record specifically states that the revised sequence (A) was submitted on September 30, 2002 and (B) replaced the earlier version of accession number AF252298 (gi:12658962). A skilled artisan had access to the chemical structure of the nucleic acids and the proteins encompassed by the current

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invention by virtue of the disclosure of the Genbank accession number in the specification as filed.

Furthermore, the present invention is distinct from the facts underlying the *Fiers v. Revel* and *Amgen v Chugai* cases, which were cited in support of the rejection. In these cases the conception date of a nucleic acid sequence was the date the actual DNA sequence was know. The cases hold that the description of methods for isolating a fragment of DNA and methods for isolating a corresponding mRNA is insufficient description of a nucleic acid sequence or an amino acid sequence encoded by the nucleic acid. In contrast, the present application does not rely on methods of isolation for identifying or describing the nucleic acid or polypeptide sequences, it discloses the sequences in the application. Therefore, the present application provides more than the mere description of the methods for isolating a DNA sequence. Thus, the holdings in *Fiers v. Revel* and *Amgen v Chugai* are not relevant to the present application. Applicants were in possession of the invention and the Genbank accession number describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

Applicants note that none of the rejections speak to the insufficiency of Genbank accession number AF252298 and no notification of informalities regarding the sequence listing was conveyed to the Applicants during prosecution. Applicants respectfully request withdrawal of the rejection.

IV.   **Rejection of Claims under 35 U.S.C. §112, second paragraph**

Claims 6, 15, and 27-34 are rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject that applicants regard as their invention. The claims are allegedly vague and indefinite for the following

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reasons: (A) claim 6 for not referencing a baseline sequence, and (B) claim 33 and 34 for lacking antecedent basis for "surface."
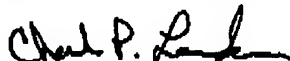
In light of the present claims the rejection is moot. Claim 6 now references Genbank accession number AF252298 and claims 33 and 34 now depend from claim 32, providing antecedent basis for surface. Applicants request the withdrawal of the rejections.

CONCLUSION

Applicants believe that the foregoing remarks fully respond to all outstanding matters for this application. Applicants respectfully request that the rejections of all claims be withdrawn so they may pass to issuance. Alternatively, Applicants request the entrance of the amendments to better prepare the claims for appeal.

The Examiner is invited to contact the undersigned patent agent at 512-536-3167 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

Charles P. Landrum, Ph.D.
Reg. No. 46,855
Agent for Applicants

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512-536-3167

Date: March 9, 2006

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<u>EXHIBIT A</u>

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Search [Nucleotide ▣] for [   ]

Limits   Preview/Index   History   Clipboard   Details

Display [GenBank ▣] Show [5 ▣][Send to ▣]

Range: from [begin   ] to [end   ]   ☐ Reverse complemented strand   Features: ☐ SNP ☒ CDD ☐

☐ 1: AF252298. Reports Ehrlichia canis 2...[gi:37528969]   Links

Comment   Features   Sequence

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KEYWORDS    .
SOURCE      Ehrlichia canis
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            Anaplasmataceae; Ehrlichia.
REFERENCE   1  (bases 1 to 4266)
  AUTHORS   McBride,J.W., Corstvet,R.E., Breitschwerdt,E.B. and Walker,D.H.
  TITLE     Immunodiagnosis of Ehrlichia canis infection with recombinant
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  JOURNAL   J. Clin. Microbiol. 39 (1), 315-322 (2001)
   PUBMED   11136790
REFERENCE   2  (bases 1 to 4266)
  AUTHORS   McBride,J.W., Comer,J.E. and Walker,D.H.
  TITLE     Novel Immunoreactive Glycoprotein Orthologs of Ehrlichia spp
  JOURNAL   Ann. N. Y. Acad. Sci. (2003) In press
REFERENCE   3  (bases 1 to 4266)
  AUTHORS   McBride,J.W. and Walker,D.H.
  TITLE     Direct Submission
  JOURNAL   Submitted (04-APR-2000) Pathology, University of Texas Medical
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REFERENCE   4  (bases 1 to 4266)
  AUTHORS   McBride,J.W. and Walker,D.H.
  TITLE     Direct Submission
  JOURNAL   Submitted (30-SEP-2002) Pathology, University of Texas Medical
            Branch, 301 University Blvd., Galveston, TX 77555, USA
COMMENT     On Oct 6, 2003 this sequence version replaced gi:12658962.
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